

REMARKS

Applicant sincerely appreciates the very detailed examination evidenced by the Official Action mailed July 7, 2005 (hereinafter "the Official Action"). Applicant also acknowledges the restriction of Claims 38-42 set out on page 2 of the Official Action. In response, Applicant has withdrawn Claims 38-42 herein.

As discussed hereinbelow in greater detail, Applicant has significantly amended independent Claim 8, adding numerous detailed recitations along the lines of those suggested by the Examiner in reference to the rejections under Section 112. For example, independent Claim 8 has been amended to further clarify how the processor circuit operates in conjunction with the release of labeled binding molecules. Applicant sincerely appreciates the Examiner's help in highlighting these areas for further clarification.

Applicant also requests the Examiner's assistance in clarifying the basis for the apparent non-examination of the claim recitations highlighted in the rejections under section 112 (amended above). Furthermore, Applicant herein respectfully requests clarification of the rejection of functional claim language solely on the basis of structures allegedly disclosed by the cited references.

In addition to the further clarifications by the amendments to independent Claim 8, Applicant has also provided remarks herein demonstrating some of the patentable distinctions of the amended claims in view of the cited references. Accordingly, Applicant respectfully requests withdrawal of the present rejections and the allowance of all claims in view of the present amendment for at least the reasons described herein.

Amended Claims 8 and 37 Comply with Section 112.

Claims 8-17 and 29-37 stand rejected under 35 U.S.C. § 112, second paragraph. *Official Action*, page 3. In particular, the Official Action objected to the recitation of the processor circuit being "configured to operate in conjunction with the release of labeled binding molecules" as recited in previously presented Claim 8. In response, Applicant has amended independent Claim 8 to recite in-part:

an optical radiation source configured for *in vivo* use that emits first optical radiation;
an optical radiation detector configured for *in vivo* use that detects second optical radiation emitted by excited labeled binding molecules; and
a processor circuit, coupled to the optical radiation source and the optical radiation detector,
wherein the processor circuit is configured to release fluorescently labeled antibodies selected to bind with predetermined Tumor Specific Antigens (TSAs),
the processor circuit is further configured to activate the *in vivo* optical radiation source after a predetermined first time interval after release of the fluorescently labeled antibodies, the predetermined first time interval selected to allow a first portion of the fluorescently labeled antibodies to bind with local available TSAs and a second portion of the fluorescently labeled antibodies to become remote from the circuit so that the first optical radiation excites the first portion of the fluorescently labeled antibodies bound with the local available TSAs and does not excite the second portion of the fluorescently labeled antibodies that become remote,
the processor circuit is further configured to sense a voltage generated by the *in vivo* optical radiation detector after a second predetermined time interval, the second predetermined time interval being after emission of the first optical radiation has ceased.

As shown above in the recitations of amended independent Claim 8, Applicant has amended the recitations associated with the configuration of the processor circuit to further clarify the operation thereof in conjunction with the release of fluorescently labeled antibodies. In particular, Claim 8 now recites that the processor circuit is configured to essentially release fluorescently labeled antibodies selected to bind with predetermined tumor specific antigens and to activate the *in vivo* optical radiation source after a predetermined first time interval after release of the fluorescently labeled antibodies. The predetermined first time interval is selected to allow the first portion of the fluorescently labeled antibodies to bind with the local available TSAs. Furthermore, the predetermined first time interval is selected to allow a second portion of the fluorescently labeled antibodies to become remote from the circuit so that the first optical radiation excites the first portion of the fluorescently labeled antibodies (*i.e.*, the ones bound with the local available TSAs) while not exciting the second portion of the fluorescently labeled antibodies that became remote (because they have not bound to

TSA's). Claim 8 has been further amended to recite that the processor circuit senses a voltage generated by the *in vivo* optical radiation detector after a second predetermined time interval. The second predetermined time interval is selected so that the processor circuit does not sense optical radiation until after the emission of the first optical radiation has ceased.

Applicant respectfully submits that the above detailed recitations added to independent Claim 8 further clarify the patentable subject matter recited therein in compliance with all sections of 112. Accordingly, Applicant respectfully requests the withdrawal of the rejections of Claim 8 under Section 112.

Applicant also wishes to point out that the detailed recitations added to independent Claim 8 do not add new matter. For example, Figure 5 of the present application shows the processor circuit 525 connected to the apparatus 580 which can be used to, for example, vibrate the matrix 580 holding the fluorescently labeled antibodies for release. Figure 5 further shows that processor circuit 525 provides a control signal A to the optical emitter 505 to control the emission of optical radiation 515. Figure 5 also shows that the processor circuit 525 receives a signal B from the optical radiation detector 510 based on the level of optical radiation 520 emitted by the excited fluorescently labeled antibodies released from the matrix material 530 under the control of the processor circuit 525.

Description of the structure and operation of the processor circuit 525 shown in Figure 5 can be found, for example, at page 13, line 5 – page 14, line 8, of the specification including a general discussion of how the optical radiation source 505, the optical radiation detector 510, and the matrix material 530 operate in conjunction with the processor circuit 525 (*see, for example, page 13, lines 23-28*).

With regard to the rejection of Claim 33, this claim has been cancelled. Accordingly, this rejection is now moot.

With regard to the rejection of Claim 37, Applicant has amended Claim 37 to recite in-part:

wherein the processor circuit is further configured to
release the unlabeled binding antibodies during a first time interval
and to release the fluorescently labeled antibodies during a second
time interval,

which further clarifies that the term "out of phase" refers to the release of unlabeled antibodies and fluorescently labeled antibodies during different time intervals. *See, for example, page 10, lines 5-8 of the specification.*

In view of the above, Applicant respectfully submits that the rejections under Section 112 have either been overcome by amendment or rendered moot by cancellation of the respective claim. Accordingly, Applicant respectfully requests that withdrawal of all rejections under Section 112 for at least the reasons described above.

Amended Independent Claim 8 is Patentable Over the Cited Art.

Independent Claim 8 stands rejected under 35 U.S.C. § 102 over U.S. Patent No. 5,833,603 to Kovacs et al. ("Kovacs") and separately over U.S. Patent No. 6,551,838 to Santini, Jr. et al. ("Santini"), and separately over U.S. Patent No. 6,343,227 to Crowley ("Crowley"). *Official Action, pages 4 and 6.*

As an initial matter it appears that the Official Action has not given any weight in examination to the recitation that the processor circuit is "configured to operate in conjunction with the release of labeled binding molecules for excitation by the first optical radiation and that receives an intensity signal associated with the intensity of the second optical radiation" as recited in previously presented Claim 8. As described above in reference to the rejections under Section 112, Applicant has endeavored to further clarify the function of the processor circuit by reciting how the processor circuit operates in conjunction with the release of labeled binding molecules as suggested by the Examiner. Accordingly, Applicant respectfully requests examination of the detailed recitations added herein in view of the cited art.

Applicant understands that under MPEP section 2173.06, two approaches to examination of claim language that the Examiner considers indefinite are possible. In the first approach, where the degree of uncertainty is not great, and where the claim is subject to more than one interpretation and at least one interpretation would render the claim unpatentable over the prior art, an appropriate course of action would be for the examiner to enter two rejections: (A) a rejection based on indefiniteness under section 112, second paragraph; and (B) a rejection over the prior art based on the interpretation of the claims which renders the prior art applicable. *See, e.g., Ex parte Ionescu, 222 USPQ 537 (Bd. App. 1984).* In the second approach where there is a great deal of confusion and

uncertainty as to the proper interpretation of the limitations of a claim, it would not be proper to reject such a claim on the basis of prior art.

Therefore, in view of the apparent non-examination of the recitations at-issue, Applicant assumes that the Examiner considered the recitation of "configured to operate in conjunction with the release of labeled binding molecules for excitation by the first optical radiation and that receives an intensity signal associated with the intensity of the second optical radiation" to be so unclear that no examination in view of the art was possible despite the description of this language in the specification. *See, for example, page 13, lines 23-28 of the specification.* Therefore, Applicants respectfully request substantive examination at least in the spirit of MPEP section 2173.06 now that the claims have been amended along the lines suggested in the Official Action.

In addition to the matters discussed above, Applicant respectfully points out that a proper rejection under Section 102 requires an identity between the claimed subject matter and the disclosure of the reference. In particular, anticipation under Section 102 requires that each and every element of the claim is found in a single prior art reference. *W. L. Gore & Associates Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983). Stated another way, all material elements of a claim must be found in one prior art source. *In re Marshall*, 198 U.S.P.Q. 344 (C.C.P.A. 1978). "Anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention." *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000). **A finding of anticipation further requires that there must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art.** *See Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Additionally, the cited prior art reference must be enabling, thereby placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964). Thus, the prior art reference must adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the invention.

In view of the above stringent standard under Section 102, Applicant respectfully submits that neither Kovacs, Santini, nor Crowley discloses the detailed recitations added to Independent Claim 8 herein. For example, although Kovacs relates to implantable

devices, there is no disclosure in Kovacs related to any kind of material release therefrom. To the contrary, the entire subject matter of Kovacs appears to relate to sensing the environment remotely and therefore does not disclose, for example, a processor circuit configured to release fluorescently labeled antibodies. Moreover, Kovacs says nothing about fluorescently labeled antibodies selected to bond with predetermined TSAs. In addition, Kovacs also does not disclose a processor circuit that is configured to activate an optical radiation source after a predetermined first time interval after the release of fluorescently labeled antibodies where the predetermined first time interval is selected to allow a first portion of the fluorescently labeled antibodies to bind with local available TSAs. Nor does Kovacs disclose a processor circuit configured to release the fluorescently labeled antibodies so that a second portion of the fluorescently labeled antibodies become remote in the circuit during the predetermined first time interval so that optical radiation excites the first portion but not the second portion due to its remoteness.

In summary, Kovacs does not disclose a processor circuit that is configured to provide the detailed timed relationship between the release of the specific type of fluorescently labeled antibodies that are selected to bind with predetermined tumor specific antigens and the subsequent optical excitation and sensing. Accordingly, independent Claim 8 is patentable over Kovacs for at least these reasons.

Independent Claim 8 is also patentable over Santini as Santini does not disclose, for example, a processor circuit configured to release fluorescently labeled antibodies selected to bind with predetermined tumor specific antigens as similarly discussed above in reference to Kovacs. Furthermore, Applicant notes that it appears that with respect to many of the dependent claims (*i.e.*, 29-34, 36 and 37), the Official Action considers that Santini discloses the detailed recitations thereof without the explicit disclosure of the details recited therein. For example, the Official Action states in part with respect to Claims 29-34, 36 and 37,

[s]ince Santini, Jr. et al. disclosed the same structures as recited in the instant claims and since Applicant has not recited any structural differences over Santini, Jr. et al. The circuit of Santini, Jr. et al. is capable of performing the limitations of the recited claims and therefore Santini, Jr. et al. anticipates the claims.
Official Action, page, paragraph 1.

Respectfully, by the logic applied by the Official Action, an unprogrammed processor circuit would anticipate any claimed processor circuit that is programmed to perform a specific task because there is no structural difference between the unprogrammed processor circuit and the programmed processor circuit. Processor circuits are naturally defined by their function, not by an apparatus type structure.

As discussed above, the standard for anticipation under Section 102 is not whether a circuit discussed in a reference is capable of performing operations that are claimed. If the present rejections are maintained on the basis of theoretical capabilities of circuits, Applicant respectfully requests that the Examiner cite an authority under which the present rejections under Section 102 may be properly maintained.¹ Applicant respectfully submits that independent Claim 8 is patentable over Santini for at least the reasons described above.

Applicant also maintains that Crowley does not disclose the recitations of independent Claim 8. For example, Crowley does not disclose a processor circuit that is configured to release fluorescently labeled antibodies selected to bind with predetermined tumor specific antigens. In fact, Crowley does not appear to discuss the release of anything, let alone antibodies selected to bind with predetermined tumor specific antigens. Furthermore, Crowley does not appear to be related to *in vivo* applications. In fact, much of Crowley relates to the deployment of optical portions thereof through lumens or trocars so that the optical portions may be inserted into the body while the remaining portions remain outside the body. Accordingly, Applicant respectfully submits that Crowley also does not disclose the recitations of independent Claim 8.

Independent Claim 8 is also patentable over Crowley as Crowley does not disclose, for example, a processor circuit configured to release fluorescently labeled antibodies selected to bind with predetermined TSAs and further, that the processor circuit is configured to activate an *in vivo* optical radiation source after a predetermined

¹ Applicant is aware of the sections of the MPEP regarding the examination of apparatus claims where a structure is defined by what it is and not what it does. *See for example*, MPEP section 2114: Apparatus and Article Claims - Functional Language. However, Applicant does not believe that MPEP section 2114 could be properly applied as the present claims are functional in nature not apparatus like. Applicant notes that the USPTO guidelines for examination of computer related inventions (MPEP 2106) also provides guidance that the processor circuit should be examined based on its function, and not strictly on structure as there may be no structural difference between a claimed processor circuit and a prior art processor circuit even though the two processor circuits are programmed to perform completely different operations.

first time interval after release of the fluorescently labeled antibodies. Crowley also does not disclose that the predetermined first time interval is selected to allow a first portion of the fluorescently labeled antibodies to bind with local available TSAs and a second portion of the fluorescently labeled antibodies to become remote from the circuit so that the first optical radiation excites the first portion of the fluorescently labeled antibodies bound with the local available TSAs and does not excite the second portion of the fluorescently labeled antibodies that become remote.

Applicant respectfully submits that independent Claim 8 is patentable over the cited references for at least the reasons described above. Furthermore, dependent Claims 9-17, 29-31, and 35-37 are patentable at least per the patentability of amended independent Claim 8 as described above.

Many of the dependent Claims are separately patentable

In addition to the reasons described above in reference to amended independent Claim 8, many of the dependent claims provide separate bases for patentability. For example, Claim 37 recites in-part that the "processor circuit is further configured to release the unlabeled binding antibodies during a first time interval and to release the fluorescently labeled antibodies during a second time interval," which is not disclosed by the cited references. As described above none of the cited references discloses fluorescently labeled antibodies, let alone releasing fluorescently labeled antibodies **and** unlabeled binding antibodies and at different times. Accordingly, Applicant submits that Claim 37 is patentable for at least these additional reasons.

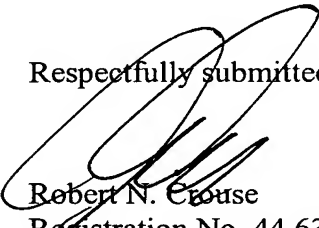
In re: Robert D. Black
Serial No.: 10/005,889
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CONCLUSION

Applicant has significantly amended independent Claim 8 in response to the Examiner's suggestion to clarify how the processor circuit operates in conjunction with the release of labeled binding molecules to overcome the rejections under section 112. Applicant has also shown that the detailed recitations added to independent Claim 8 also distinguish over the cited art. Accordingly, Applicant respectfully requests the withdrawal of all rejections and the allowance of all claims in due course. If any informal matters arise, the Examiner is strongly encouraged to contact the undersigned by telephone at (919) 854-1400.

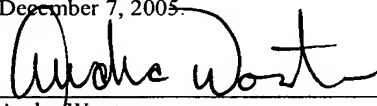
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